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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/083,413	02/27/2002	Avraham J. Domb	Q63391	7369

7590 08/17/2004

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EXAMINER	
FLOOD, MICHELE C	
ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 08/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/083,413	DOMB ET AL.	
	Examiner	Art Unit	
	Michele Flood	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-12 and 14-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-12 and 14-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the preliminary amendment filed on June 9, 2004, and the subsequent amendment to the preliminary amendment filed on July 22, 2004. Acknowledgment is made of Applicant's cancellation of Claims 13 and 27-34.

The finality of the rejection made in the previous Office is withdrawn, as the preliminary amendment filed on June 9, 2004 was received in the Office prior to the mailing of the Final Office action dated June 15, 2004.

Claims 1-4, 6-12 and 14-26 are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6-12 and 14-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a solid, self-bioadhesive composition for topical application that adheres to oral mucosal tissue comprising (a) a therapeutically effective amount of a least one herbal active (b) a pharmaceutically acceptable solid bioadhesive carrier; and (c) Carnallite or a salt of Carnallite, does not reasonably provide enablement for a solid, self-bioadhesive composition for topical application that adheres to oral mucosal tissue comprising (a) a therapeutically effective amount of a least one homeopathic active agent (b) a pharmaceutically acceptable solid bioadhesive

carrier; and (c) Carnallite or a salt of Carnallite. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, as broadly claimed.

The claims are drawn to a solid, self-bioadhesive composition for topical application that adheres to oral mucosal tissue comprising: (a) a therapeutically effective amount of a least one herbal active agent or homeopathic active agent, wherein the herbal active agent is selected from the group consisting o a bioactive herb extract, a tincture, an essential oil and mixtures thereof; (b) a pharmaceutically acceptable solid bioadhesive carrier in an amount from about 40 to 99 percent based on the weight of the whole composition; and (c) Carnallite or a salt of Carnallite.

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of one of ordinary skill in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation added to make or use the invention based on the content of the disclosure. While all of these factors are considered, a sufficient number are discussed below so as to create a *prima facie* case.

The specification broadly discloses a solid, self-bioadhesive composition for topical application that adheres to oral mucosal tissue comprising a

therapeutically effective amount of a homeopathic active agent for the treating mucosal disorders. The specification is non-enabling for the claim designated composition as the specification does not provide guidance as to how to identify any and all ingredients used in the making of a homeopathic agent, and how to determine the effective therapeutic amounts of a homeopathic agent for use in the making of the claimed composition. While the specification has reasonably demonstrated a method of making the claim-designated composition comprising a therapeutically effective amount of an herbal bioactive agent, other than the mere description for the general preparation of a homeopathic medicine for use in the treatment of a bacterial infections in [0141] to [0142], the specification does not adequately describe the source of the ingredients, the amounts of the ingredients or the therapeutically effective amounts of the ingredients to result the effect for incorporating a therapeutically effective amount of an homeopathic agent into the making of the claim-designated composition.

At the time the invention was filed, the state of the art did not fully support the incorporation of homeopathic agents into the making of pharmaceutical compositions that were intended for the purpose of administration to humans to provide a therapeutic result in the treatment of disease conditions. *See* the 1999 quackwatch.com website reference titled "Homeopathy: The Ultimate Fake" by Dr. Stephan Barrett. Even by Applicant's own admission, it would at least appear that the determination for the administration of a therapeutically effective amount of a homeopathic agent is at best a matter of trial and error to provide an

effective means for treating mucosal disorders suffered by humans, as set forth in the disclosure of [0137].

Inventions targeted for therapy in living subjects should provide evidence because of the unpredictability in biological responses to therapeutic treatments. Claims drawn to pharmaceutically acceptable compositions require supporting evidence, which clearly define the ingredients or constituents therein, and supporting data because of the unpredictability in biological responses to therapeutic treatments. In order to enable the skilled artisan to practice the invention as claimed, Applicant would have to describe the effective amounts of each ingredient for the administration of the composition intended for a therapeutic treatment. There is no guidance in the specification, other than the aforementioned composition comprising a therapeutically effective amount of at least one herbal active agent. Given the insufficient guidance in the specification as to what ingredients encompass a "homeopathic agent", and the effective amounts of the ingredients to provide a therapeutically effective amount of a homeopathic agent, the lack of working examples, the lack of correlative working examples, the claims would require an undue amount of experimentation without a predictable degree of success on the part of the skilled artisan.

Accordingly, it would take undue experimentation without a reasonable expectation of success for the skilled artisan to identify any and all ingredients used in the making of a homeopathic agent, and how to determine the effective therapeutic amounts of a homeopathic agent for use in the making of the claimed

solid, self-bioadhesive composition for topical application that adheres to oral mucosal tissue, as broadly claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 6-12 and 14-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of Claims 1, 14 and 24 are rendered indefinite the term "homeopathic active agent" because it is unclear as to what Applicant intends to direct the subject matter of the invention. Does the term "homeopathic active agent" encompass a homeopathic protein composition or a homeopathic interleukin composition or a homeopathic RNA composition or a homeopathic bee pollen composition?

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The

fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michele C. Flood.

MICHELE FLOOD
PATENT EXAMINER

MCF
August 10, 2004